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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,869	03/26/2004	Osama Kandil	KAN-001-B	7603

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,869	KANDIL, OSAMA	
	Examiner	Art Unit	
	Samira Jean-Louis	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 12-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 1-29 are pending in the application and are being examined on the merits herein.

Applicant's election with traverse to various species in the reply filed on 08/10/07 is acknowledged. The traversal is on the ground(s) that the search of all the groups and species does not impose an undue burden upon the examiner. This is not found persuasive because the claims recited in the instant application recite a multiplicity of methods and species of said composition that are contrastingly different in nature and would therefore be classified in different fields. In addition, applicant indicated that the disclosed species are part of a Markush claim and consequently are related and therefore would not entail a serious search burden. The examiner respectfully disagrees with such statement given that the species of said group encompass various diverse species that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). Thus, in this instance, these species are patentably distinct and fully capable of supporting separate patents. Furthermore, given that the claims recite such a multiplicity of species, the search would indeed be unduly extensive and burdensome given that a search for these species would consist of searching multiple databases for various references and literature searches.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, and 12-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain skin conditions such as fungal and/or bacterial skin infections, does not reasonably provide enablement for a method to prevent all skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Importantly, given that the term "prevention" implies an absolute term, it is assumed that no known disease can be absolutely prevented at this time. For example, applicant does not reasonably provide enablement for a method to prevent all skin conditions nor does the

application enable any person skilled in the art to use the invention to every skin conditions.

The instant claims are drawn to a method of treating and preventing skin condition by topically administering a semi-solid composition comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention.

Attention is directed to *In reWands,* 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Specifically, in regard to the breadth of the claims, the predictability of the art, and the amount of guidance of direction or working examples, claims 9-11, and 26-29 fail to embrace and read on preventing every and/or any skin condition by topically administering a semi-solid composition as set forth in the instant specification. In addition, the predictability of preventing a skin condition is relatively low given that the prevention of all skin conditions would entail different mechanisms of actions.

Therefore, to one skilled in the art, prevention of a skin condition is highly unpredictable. As for the guidance of the specification as to the prevention of a skin condition, the above is completely lacking given that the specification is solely limited to treatments of specific types of skin conditions (i.e. fungal infection, bacterial infection) and not for prevention of any skin conditions.

In conclusion, the applicant is enabled for a method of treating fungal or bacterial skin conditions, but not for the prevention of any skin condition.

The claims are examined herein for a method of treating a skin condition.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, and 26-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain skin conditions such as fungal and/or bacterial skin infections, does not reasonably provide enablement for a method to treat all skin conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, skin cancer or Kaposi sarcoma would both be considered as types of skin

conditions, yet applicant does not reasonably provide enablement for a method to treat skin cancer or Kaposi.

The instant claims are drawn to a method of treating and preventing skin condition by topically administering a semi-solid composition comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa L.* seeds and a pharmaceutically acceptable carrier. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention.

Attention is directed to *In reWands,* 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman,* 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Specifically, in regard to the breadth of the claims, the predictability of the art, and the amount of guidance of direction or working examples, claims 9-11, and 26-29 fail to embrace and read on treating every skin conditions by topically administering a semi-solid composition as set forth in the instant specification. The term "skin condition" reads on a divergent group of diseases, such as skin cancer or Kaposi sarcoma, diaper rash, etc., yet, the specification does not enable the prevention of skin cancer or Kaposi

sarcoma, various types of skin conditions. In addition, the predictability of preventing a skin condition is relatively low given that the various known skin conditions are characterized by divergent etiologies. Therefore, to one skilled in the art, prevention of a skin condition is highly unpredictable. As for the guidance of the specification as to the prevention of a skin condition, the above is severely limiting given that the specification is limited to a certain specific types of skin condition (i.e. fungal infection, bacterial infection) and not necessarily skin cancer, for example.

In conclusion, the applicant is enabled for a method of treating fungal or bacterial skin conditions (i.e. diaper rash), but not for the treatment of any skin condition.

The claims are examined herein for a method of treating diaper rash.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 11, and 26 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1) in view of Berg (Advances in Dermatology, 1988, pg. 75-98).

Ahmad et al. teaches a method of treating skin diseases comprising using compositions derived from extracts of *Nigella sativa L.* seeds in an amount no less than 20% w/v (see abstract and summary of invention, paragraph 25, lines 1-2). Specifically, this method of treatment further provides for a pharmaceutical composition of Nigella sativa (about 1% to 95% by weight-see paragraph 21, page 3) for treatment of skin diseases (see summary of invention, paragraph 19, lines 1-3, page 3) and for topical delivery (see summary of the invention, paragraph 19, lines 1-3 and line 43, page 3). Furthermore, the composition of Ahmad et al. may be formulated as a hydrogel lotion or cream (see paragraph 92, lines 1-3, page 11), which reads on a semi-solid composition.

Ahmad et al. does not specifically teach a method of treating a skin condition such as diaper rash with a specific range of polyunsaturated fatty acids free of saturated fatty acids and glyceryl esters.

Berg teaches that common diaper dermatitis (i.e. diaper rash) entails a group of skin disorder and therefore would qualify as a skin disease as disclosed by Ahmad et al (instant claim 11).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Ahmad et al. with the knowledge of dermatitis provided by Berg to arrive at the method of applicant since Ahmad et al. in view of Berg essentially teaches a method of treating diaper rash using a semi-solid

composition (i.e. cream or lotion) *of Nigella L. sativa.* Given that Ahmad teaches a method of treating a skin disease (i.e. diaper rash-see Berg reference) using *Nigella sativa L.* seeds and Berg discloses that diaper rash is a type of skin disease, one of ordinary skill would have been motivated to combine the method of Ahmad et al. with the disclosure of Berg with the expectation of providing a topical composition that is semi-solid and skin moisturizing, revitalizing and analgesic effects to treat diaper rash comparable to applicant's invention.

Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1) in view of Berg (Advances in Dermatology, 1988, pg. 75-98) as applicable to claims 9-11, 26 above and in further view of Nickavar et al. (Z. Naturforsch. 2003, Vol. 58c, pg. 629-631).

As for the term "consisting essentially of" limitation in claim 28, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

The Ahmad and Berg references are as discussed above. However, Ahmad and Berg do not address the particular components and percentages of the polyunsaturated fatty acid fraction.

Nickavar et al. teaches a chemical composition of the fixed oil (i.e. saponified fraction-see figure 2 of applicant) of *Nigella sativa L.* comprising 23.4% of oleic acid (i.e. octadecenoic acid) and 55.6% of linoleic acid (i.e. octadecadienoic acid)(instant claims 28-29). Nickavar has been provided to demonstrate that the quantity of Nigella sativa L extract utilized by Ahmad et al. provides a composition within the range of applicant's composition containing the polyunsaturated fatty acid fraction in an amount no less than 16.5% (addition of [20.4, 55.6, 0.4, 3.1] x 20%).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the method of Ahmad in view of the knowledge of dermatitis provided by Berg and as evidenced by Nickavar et al. (given the specific components and ranges disclosed by Nickavar) to arrive at the method of applicant. Given that Ahmad teaches a method of treating a skin disease (i.e. diaper rash-see Berg reference) using *Nigella sativa L.* seeds, and Berg discloses that diaper rash is a type of skin disease, and Nickavar discloses the intrinsic ranges and composition of the *Nigella L. sativa* seeds, one of ordinary skill would have been motivated to utilize the method of Ahmad et al. with the disclosures of Berg and Nickavar with the expectation of providing

a semi-solid topical composition that is mainly composed of 23.4% oleic acid and 55.6% linoleic acid.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmad et al. (U.S. 2005/0058735 A1) in view of Berg (Advances in Dermatology, 1988, pg. 75-98) as applicable to claims 9-11, 26 above and in further view of Schlenk et al. (J. of Amer. Chem. Soc. 1950,Vol. 72, pg. 5001-5004) and Ali et al. (Phyt. Ther. Res. Vol. 17, pg. 299-305).

The Ahmad and Berg references are as discussed above. However, Ahmad and Berg do not address a polyunsaturated fatty acid fraction of Nigella L. sativa seeds free of saturated fatty acids, sterols, volatile oils and glyceryl esters.

Schlenk et al. teaches a method of extracting polyunsaturated acid fraction using a urea complex to yield a polyunsaturated fatty acid fraction devoid of saturated fatty acids and glyceryl esters (instant claim 27).

Ali et al. further teaches that the *Nigella L. sativa* seeds that the polyunsaturated fatty acids contains biological activity due to the presence of thymoquinone (see abstract) and has been found to be a natural remedy for a number of illnesses and conditions. Specifically, Ali et al. teaches that the therapeutic value and pharmacological effects of the seeds lies in the fixed oil (i.e. the polyunsaturated fatty acid fraction) (see pg. 300, colum 2, lines, 5-10, 28-30).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Ahmad et al. with the method of Schlenk et al. to arrive at the method of applicant since the therapeutic value of the Nigella sativa L. seeds also lie in the polyunsaturated fatty acid fraction and thus this concentrated fraction would be more suitable for pharmaceutical uses as evidenced by Ali et al. Given that Ahmad teaches a method of treating a skin disease (i.e. diaper rash-see Berg reference) using *Nigella sativa L.* seeds comprising topically administering an extract of *Nigella sativa L.* seeds in the form of a lotion or a cream (i.e. semi-solid) and Schlenk et al. teaches a method of obtaining purified polyunsaturated fatty acids, and Ali discloses the purpose of using the polyunsaturated fatty acid fraction, one of ordinary skill would have been motivated to combine the method of Ahmad et al. with the method of Schlenk et al. in view of Ali with the expectation of providing a topical composition that is semi-solid and skin moisturizing, revitalizing and analgesic effects comparable to that disclosed in applicant's invention.

Regarding the skin moisturizing, revitalizing and analgesic effects as recited in claim 10, it is considered that one of ordinary skill in the art at the time of the invention was made would have found it obvious to conclude that the method of treating a skin condition using the extract composition of Ahmad et al. combined with the method of Schlenk et al. would possess the same sensory and pharmacokinetic profiles as that

disclosed by the applicant given that these characteristics are inherent of the said *Nigella sativa L.* seeds.

It is noted that In re Best,195 USPQ 430, and In re Fitzgerald, 205 USPQ 594, discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

Claims are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

08/27/2007

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER